UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,915	09/07/2000	Larry I. Benowitz	CMZ-129	2385

826 7590 08/18/2003

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	13

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/656,915	Applicant(s) BENOWITZ, LARRY I.
	Examiner Christopher Nichols, Ph.D.	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 02 April 2003 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-3** and **7-24** (each in part), drawn to a method for treating a subject suffering or prone to suffering from a condition characterized by aberrant axonal outgrowth of central nervous system neurons, comprising administering to said subject a compound that modulates the activity of N-kinase, thereby treating the subject wherein said condition is spinal cord injury, classified in class 514, subclass 2, for example.

II. Claims **1, 4, 5,** and **7-24** (each in part), drawn to a method for treating a subject suffering or prone to suffering from a condition characterized by aberrant axonal outgrowth of central nervous system neurons, comprising administering to said subject a compound that modulates the activity of N-kinase, thereby treating the subject wherein said condition is epilepsy, classified in class 514, subclass 2, for example.

III. Claims **1** and **6-24** (each in part), drawn to a method for treating a subject suffering or prone to suffering from a condition characterized by aberrant axonal outgrowth of central nervous system neurons, comprising administering to said subject a compound that modulates the activity of N-kinase, thereby treating the subject wherein said condition is neuropathic pain syndrome, classified in class 514, subclass 2, for example.

IV. Claims **25-29**, drawn to a method for modulating axonal outgrowth of a central nervous system neuron, comprising contacting the central nervous system neuron with a compound that modulates the activity of N-kinase, thereby modulating axonal outgrowth of the central nervous system neuron, classified in class 514, subclass 2, for example.

V. Claims **30-38**, drawn to a method for identifying a compound that modulates axonal outgrowth of a central nervous system neuron, comprising contacting N-kinase with a test compound and determining the ability of the test compound to modulate the activity of N-kinase, thereby identifying a compound that modulates axonal outgrowth of a central nervous system neuron, classified in class 435, subclass 500, for example.

VI. Claims **39-46**, drawn to a method for identifying a compound that modulates axonal growth of a central nervous system neuron, comprising contacting N-kinase with a test compound, an N-kinase substrate, a radioactive ATP, and Mn^{+2}; and determining the ability of the test compound to modulate N-kinase dependent phosphorylation of the substrate, thereby identifying a compound that modulates axonal outgrowth of a central nervous system neuron, classified in class 435, subclass 500, for example.

VII. Claim **47**, drawn to a compound that modulates axonal outgrowth of a central nervous system neuron identified by the method of claim 30, classification dependent upon agent structure.

VIII. Claim **48**, drawn to a compound that modulates axonal outgrowth of a central nervous system neuron identified by the method of claim 39, classification dependent upon agent structure.

IX. Claims **49** and **53-57**, drawn to an isolated N-kinase polypeptide, classified in class 530, subclass 300, for example.

X. Claims **50-52**, drawn to an antibody, classified in class 530, subclass 387.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, IV, V, and VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of treating *spinal cord injury*, which is not required by any of the other Inventions. Invention II requires search and consideration of treating *epilepsy*, which is not required by any of the other Inventions. Invention III requires search and consideration of treating *neuropathic pain syndrome*, which is not required by any of the other Inventions. Invention IV requires search and consideration of modulating axonal outgrowth, which is not required by any of the other Inventions. Invention V requires search and consideration of screening test compounds that *modulate* N-kinase activity, which is not required by any of the other Inventions. Invention VI requires search and consideration of screening test compounds

that modulate N-kinase dependent *phosphorylation of a substrate*, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions VII, VIII, IX, and X are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The compound of Invention VII can be prepared by processes which are materially different from use of the compound of Invention VIII, the polypeptide of Invention IX, or the antibody of Invention X, such as by chemical synthesis, or by isolation and purification from natural sources. The compound of Invention VIII can be prepared by processes which are materially different from use of the compound of Invention VII, the polypeptide of Invention IX, or the antibody of Invention X, such as by chemical synthesis, or by isolation and purification from natural sources. The polypeptide of Invention IX can be prepared by processes which are materially different from use of the compound of Invention VII, compound of Invention VIII, or the antibody of Invention X, such as by chemical synthesis, by isolation and purification from natural sources, or recombinant expression systems. The antibody of Invention X can be used in materially different methods other than to isolate the polypeptide of Invention IX, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The antibody of Invention X can be made and used without either the compound of Invention VII or the compound of Invention VIII.

5. Invention VII and each of Inventions I, II, III, IV, and VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Invention VII can be used to isolate the polypeptide of Invention IX.

6. Invention VIII and each of each of Inventions I, II, III, IV, and V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Invention VIII can be used to isolate the polypeptide of Invention IX.

7. Inventions IX and each of Inventions I, II, III, IV, V, and VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention IX can be used to make the antibody of Invention X.

8. Inventions V and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

compound of Invention VII can be made through materially different methods such as chemical synthesis or purification/isolation from natural sources.

9. Inventions VI and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compound of Invention VIII can be made through materially different methods such as chemical synthesis or purification/isolation from natural sources.

10. Inventions X and each of I, II, III, IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions X and each of I, II, III, IV, V, and VI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, III, IV, V, and VI do not recite the use or production of the antibody of Invention X.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
August 15, 2003

(4) A claim being canceled must be listed in the claim listing with the status identifier "canceled"; the text of the claim must not be presented. Providing an instruction to cancel is optional.

(5) Any claims added by amendment must be presented in the claim listing with the status identifier "(new)"; the text of the claim must not be underlined.

(6) All of the claims in the claim listing must be presented in ascending numerical order. Consecutive canceled, or not entered, claims may be aggregated into one statement (*e.g.*, Claims 1 – 5 (canceled)).

Example of listing of claims (use of the word "claim" before the claim number is optional):

Claims 1-5 (canceled)

Claim 6 (previously presented): A bucket with a handle.

Claim 7 (withdrawn): A handle comprising an elongated wire.

Claim 8 (withdrawn): The handle of claim 7 further comprising a plastic grip.

Claim 9 (currently amended): A bucket with a ~~green~~ blue handle.

Claim 10 (original): The bucket of claim 9 wherein the handle is made of wood.

Claim 11 (canceled)

Claim 12 (not entered)

Claim 13 (new): A bucket with plastic sides and bottom.

B) Amendments to the specification:

Amendments to the specification, including the abstract, must be made by presenting a replacement paragraph or section or abstract marked up to show changes made relative to the immediate prior version. An accompanying clean version is not required and should not be presented. Newly added paragraphs or sections, including a new abstract (instead of a replacement abstract), must not be underlined. A replacement or new abstract must be submitted on a separate sheet, 37 CFR 1.72. If a substitute specification is being submitted to incorporate extensive amendments, both a clean version (which will be entered) and a marked up version must be submitted as per 37 CFR 1.125.

The changes in any replacement paragraph or section, or substitute specification must be shown by underlining (for added matter) or strikethrough (for deleted matter) with 2 exceptions: (1) for *deletion of five characters or fewer, double brackets may be used (e.g., [[eroor]]); and (2) if strikethrough cannot be easily perceived (e.g., deletion of the number "4" or certain punctuation marks), double brackets must be used (e.g., [[4]]). As an alternative to using double brackets, however, extra portions of text may be included before and after text being deleted, all in strikethrough, followed by including and underlining the extra text with the desired change* (e.g., ~~*number 1 as*~~ *number 14 as)*

C) Amendments to drawing figures:

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments or remarks, section of the amendment, *and may be accompanied by a marked-up copy of one or more of the figures being amended, with annotations.* Any replacement drawing sheet must *be identified in the top margin as "Replacement Sheet"* and include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. *Any marked-up (annotated) copy showing changes must be labeled "Annotated Marked-up Drawings" and accompany the replacement sheet in the amendment (e.g., as an appendix).* The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Questions regarding the submission of amendments pursuant to the revised practice set forth in this flyer should be directed to: Elizabeth Dougherty or Gena Jones, Legal Advisors, or Joe Narcavage, Senior Special Projects Examiner, Office of Patent Legal Administration, by e-mail to patentpractice@uspto.gov or by phone at (703) 305-1616.